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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,581	07/11/2001	Charles W. Hewitt	266/156	8315

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/903,381

Applicant(s)  
Hewitt

Examiner  
Sandra Saucier

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 5, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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**DETAILED ACTION**

Claims 1-22 are pending and are considered on the merits.

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 uses the word “equivalent”. It is uncertain if applicant intends to mean that the claimed composition is limited to tissue equivalents, such as the well known living skin equivalents or not.

Claims 2-22 use “the tissue”. It is unclear if this refers to subject’s tissue or the “equivalent” tissue, as two types of tissue appear in the independent claim.

Claim 11 should be “comprises culturing”, not “further comprises”.

Claims 16 and 19 are unclear. It cannot be determined if the composition now comprises three tissue segments. It should state, “further comprising another (equivalent?) tissue segment which ...” if applicant intends this embodiment to contain at least three tissue segments. In the interest of compact prosecution, it is assumed that three segments of equivalent tissue are in the composition.

Claims 20-22 are unclear. Is the tissue claimed now a processed histological/TUNEL stained, etc. sample, or is this the next step in the intended use of the sample. In the interest of compact prosecution and in the absence of any further components of the composition, this phrase is considered to be a further intended step of processing the tissue of claim 1, particularly because no concrete components or descriptors of the tissue are present.

***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or

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described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15, 17-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Doolin *et al.* [AL].

The claims are directed to a composition with the intended use of being apoptosis standards. The composition comprising a tissue that has been subjected to a treatment that reproducibly results in a predetermined, measurable amount of apoptosis. The composition as claimed need only be a tissue that has undergone a stressor that induces apoptosis. Practically all levels of induced apoptosis are measurable by well known, commercially obtainable means. If one treats a similar piece of tissue to the same stressor, one would reasonably expect to induce the same amount of apoptosis.

Please note that these are not method claims, nor are they product by process claims, they are claims merely to a piece of tissue that has been traumatized in some reproducible manner so as to induce apoptosis. The limitations of claims 2-14 simply describe either inherent properties of the tissue or attempt to introduce process claims into a product claim. It does not matter how the product is produced, merely that it would have the same characteristics as the prior art product.

Please note that the tissue cited in the prior art would have all of the claimed characteristics and that intended use of a composition and how those inherent characteristics are measured or induced is of little patentable weight.

The references are relied upon as explained below.

Doolin *et al.* disclose living skin equivalent which has been reproducibly thermally injured. Thermal injury to LSE tissue induces measurable apoptosis. Control segments have not been thermally injured, thus claim 15 is anticipated by the disclosure of CON and BCON, which are two tissue segments.

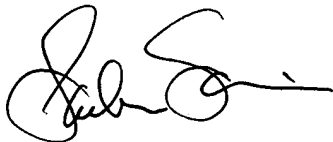
Further, with regard to claim 17, written instructions reciting an alleged novel use of a composition do not change the composition itself. *See, e.g., In re Haller* 73 USPQ 403, at 404 (CCPA 1947). ("Accordingly, the mere labeling of an old composition as an insecticide does not make it a new or different composition within the meaning of the patent statutes.").

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Claim 16 appears to be directed to patentable subject matter.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
April 17, 2003